

### **REMARKS**

The amendments presented above mirror amendments made to the parent application during prosecution.

We thank the Examiner for the courtesies extended during the telephonic Interview conducted with the undersigned on March 3, 2004. In accordance with the recommendation of the Examiner during the Interview, the amendment to replace the Sequence Listing with the substitute Sequence Listing, which mirrors an amendment made to the parent application during prosecution, is presented herewith for completeness.

The substitute Sequence Listing is presented in accordance with a teleconference conducted during prosecution of the parent application between Tim Tracy of our firm and the prior Examiner (Examiner Stole) on June 23, 1999. During this teleconference, Mr. Tracy explained to Examiner Stole that the Sequence Listing originally filed in the parent application contained three typographical errors (identified in detail below). Mr. Tracy discussed with Examiner Stole what evidence would be required to correct the typographical errors. Based on this discussion, and a follow-up discussion between Kevin Hooper of this firm and Examiner Stole on May 16, 2001, the applicants undertook costly and time-intensive lab work to demonstrate that the errors in the Sequence Listing originally filed in the parent application are typographical in nature and that one skilled in the art would readily recognize these errors and how to remedy them by sequencing the clone identified in the present application, which is publicly available. (See *In re Oda*, 170 USPQ 268 (CCPA 1971)).

The substitute Sequence Listing corrects the following three typographical errors present in the Sequence Listing originally filed in the parent application:

(1) the nucleotide at position 852 of SEQ ID NO:1 has been changed from "G" to --C--;

(2) the nucleotide at position 644 of SEQ ID NO:3 has been changed from "A" to --C--; and

(3) the amino acid at position 192 of SEQ ID NO:7 has been changed from "Asn" to --Thr--.

The corrections contained in the substitute Sequence Listing are supported by the deposit of the strain from which SEQ ID NOs: 1, 3 and 7 were obtained under the terms of the Budapest Treaty at the Deutsche Sammlung Von Mikroorganismen, Grisebachstrasse, D-3400 Gottingen, Germany, under Deposit No.: DSM 4025 on March 17, 1987, and the reference to the deposit in the specification (see page 8, lines 9-11).

The evidence supporting the requested correction is submitted concurrently herewith in the form of declarations by the scientist who commissioned the sequencing on behalf of the applicants, and employees of independent cloning and sequencing companies who cloned and sequenced the relevant parts of the deposited clone. See Exhibits C-F.

Claims 4-8, 10-19, 23, 24, 26 and 27 have been cancelled without prejudice. Of the remaining pending claims, claims 1-3 and 9 are directed to Group I and claims 20-22, 25 and 28 are directed to Group IV as set forth in the Restriction Requirement issued in the parent application on August 28, 2001. (See Paper No. 13).

The Restriction Requirement divided the claims into the following allegedly distinct inventions:

Group I drawn to drawn to “an enzyme comprising a recombinant polypeptide having alcohol and aldehyde dehydrogenase activity” containing claims 1-3 and 9; Group II drawn to “DNA encoding said enzyme, expression vectors, recombinant host, and recombinant production of the enzyme” containing claims 4-8 and 10-16; Group III drawn to “production of aldehyde, alcohol and carboxylic acid in fermentor [sic]” containing claims 17-19, 23, 24, 26 and 27; and Group IV drawn to “production of aldehyde, alcohol and carboxylic acid by the enzyme in vitro” containing claims 20-22, 25 and 28. (Paper No. 12 at 2-3).

We note that in the parent application, Groups II and III, which the Examiner acknowledged were related as product and process of use, were rejoined by the Examiner “[p]ursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996, (1184 O.G. 86)” upon finding the claims directed to the product allowable. (See Notice of Allowability at 2-3). It is respectfully submitted that Groups I and IV, which the Examiner acknowledged are also related as product and process of use (see Paper No. 13 at 3), warrant equivalent treatment. Accordingly, the claims of both Groups I and IV are presented herewith for examination on the merits.

Claims 1, 2 and 25 have been amended for the sake of clarity to insert a colon after each occurrence of the term “SEQ ID NO” and the respective numerical identifiers. It is submitted that this amendment is formal in nature and does not change the scope of the claims in any manner.

Claims 1, 2 and 25 have further been amended to remove the recitation of amino acid sequences "which contain addition, insertion, deletion and/or substitution of one or more amino acid residues in said sequence." Support for this amendment is found in original claims 1, 2 and 25 and in the specification at, for example, page 3, lines 18-21, and page 17, lines 14-17. *See, In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01 (o) and (l).

Claims 1, 2 and 25 have also been amended to recite "a polypeptide with at least 80% identity to SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7 or SEQ ID NO: 8." Support for this amendment is found in the specification at, for example, Table 7 entitled *Homologies of amino acid sequences among AADHs* on page 34, lines 14-19.

Claim 3 has been amended for the sake of clarity to remove the recitation of "at least one of" and to replace the term "and" with the term "or." It is submitted that this amendment is formal in nature and does not change the scope of the claim in any manner.

Claim 9 has been amended to recite the limitations of cancelled claim 8. Support for this amendment is found in original claims 8 and 9. *Id.*

Claim 9 has further been amended for the sake of clarity to replace the recitation of "encoded by at least one DNA molecule of" with "produced by." It is submitted that this amendment is formal in nature and does not change the scope of the claim in any manner.

Claim 29 has been added. Support for this claim is found in original claim 1 and in the specification at, for example, page 3, lines 18-21, and page 17, lines 14-17. *Id.*

Claim 30 has been added. Support for this claim is found in original claim 7 and in the specification at, for example, page 5, lines 1-9, and page 17, lines 19-25. *Id.*

Claim 31 has been added. Support for this claim is found in original claim 8 and in the specification at, for example, page 5, lines 1-9, page 17, lines 19-25 and Table 7 on page 34, lines 14-19. *Id.*

#### **Substitute Sequence Listing**

In accordance with comments made by prior Examiner Stole during telephonic Interviews ("Parent Interviews") conducted during prosecution of the parent application with Tim Tracy and Kevin Hooper of our offices on June 23, 1999 and May 16, 2001, respectively, the Specification has been amended to replace the existing Sequence Listing with a substitute Sequence Listing that corrects three typographical errors, as set forth above. A paper copy of the Sequence Listing is attached hereto as Exhibit A and a computer readable form of the Sequence Listing is attached hereto as Exhibit G.

In accordance with 37 CFR § 1.825(b), upon information and belief, the content of the paper copy and the computer readable form of the Sequence Listing submitted herewith are identical.

In support of the corrections embodied in the substitute Sequence Listing and as requested by the Examiner during the Parent Interviews, we have attached a copy set of the following documents as Exhibits C-F, respectively: the First Declaration of Dr. Masako Shinjoh under 37 C.F.R. §1.132 ("First Shinjoh Declaration"), the Second Declaration of Dr. Masako Shinjoh under 37 C.F.R. §1.132 ("Second Shinjoh Declaration"), the Declaration of Mr. Yoshitaka Murata under 37 C.F.R. §1.132 ("Murata Declaration"), and the Declaration of Mr. Masao Mashita under 37 C.F.R. §1.132 ("Mashita Declaration").

Dr. Shinjoh, a genetic engineer at Nippon Roche Research Center of Nippon Roche K.K. ("Roche") and a coinventor of the instant application (see First and Second Shinjoh Decls. ¶¶ 1 and 2), attested that after the parent application was filed she became aware of the following typographical errors in the originally filed Sequence Listing:

- (1) the nucleotide at position 852 of SEQ ID NO:1 is a "G," but it should be a "C";
- (2) the nucleotide at position 644 of SEQ ID NO:3 is an "A," but it should be a "C"; and
- (3) the amino acid at position 192 of SEQ ID NO:7 is "Asn," but it should be "Thr".

(See Second Shinjoh Decl. ¶¶ 4-9). In accordance with Examiner Stole's guidance, to confirm these errors, Dr. Shinjoh commissioned the independent sequencing of strain DSM 4025, the same strain from which SEQ ID NOs: 1 and 3 were isolated, and from which SEQ ID NO: 7 was derived. (See page 17, lines 14-17 and Example 1 on pages

27-33). The deposit of strain DSM 4025 is specifically referenced in the specification. (See page 8, lines 9-11).

Dr. Shinjoh obtained a sample of strain DSM 4025 from the Deutsche Sammlung Von Mikroorganismen und Zellkulturen GmbH ("DSMZ") (see Second Shinjoh Decl. at ¶¶ 6-9). Dr. Shinjoh then forwarded the sample of DSM 4025 to Mr. Masao Mashita for sequencing at an independent cloning and sequencing company. (See First Shinjoh Decl. ¶¶ 10-12).

Mr. Mashita, Sales & Marketing Director at Sawady Technology Co., Ltd. (see Mashita Decl. ¶ 1), then forwarded the sample of DSM 4025 received from Dr. Shinjoh to Mr. Yoshitaka Murata at another company independent from Roche for the isolation of chromosomal DNA (see *Id.* ¶¶ 6 and 7). Mr. Murata, a scientist at K.K. Kyurin Corporation (see Murata Decl. ¶ 1), supervised the isolation of chromosomal DNA from the sample of DSM 4025 and forwarded the isolated DNA to Mr. Mashita (see *Id.* at ¶¶ 7-10). Mr. Mashita then supervised the sequencing of the DNA (see Mashita Decl. ¶¶ 8 and 9) and forwarded the resulting sequence to Dr. Shinjoh (see *Id.* at ¶ 10).

Upon receipt of the nucleotide sequence obtained from DSM 4025, Dr. Shinjoh was able to confirm that in fact, the Sequence Listing originally filed with the parent application contained the aforementioned three errors. (Second Shinjoh Decl. ¶¶ 16-20).

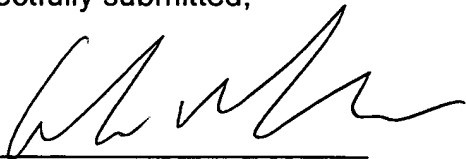
As the Federal Circuit has recently confirmed, reference in a patent specification to a deposit of genetic material is sufficient to fully describe that material. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1614 (Fed. Cir. 2002)

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("[R]eference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement."). In view of the reference to the deposit of strain DSM 4025 in the specification (see page 8, lines 9-11); the Declarations submitted herewith and the discussions with the Examiner during the Parent Interviews, the identified errors would have been obvious to one skilled in the art as well their remedy. Thus, the proposed corrections are not new matter. (*In re Oda*, 170 USPQ at 271). Accordingly, entry and approval of the substitute Sequence Listing correcting the aforementioned errors is respectfully requested.

In view of the foregoing, entry of the amendments in advance of prosecution on the merits, and allowance of all claims respectfully, is requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

Respectfully submitted,

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